

Remarks/Arguments

I. Status and Nature of the Amendments

Claims 2 and 4-26 were previously pending. Claims 1 and 3 have been previously cancelled. Claims 5-11 and 15-24 have been withdrawn in light of a restriction requirement. Applicants have cancelled claims 2, 4, and 12-14, and added new claims 27-35. Accordingly, claims 25-35 are pending and under Examination.

The Examiner has objected to claims 2, 4 and 12-14 as depending from base claims of higher number. Accordingly, these claims have been cancelled and new claims 27-33 have been introduced. New claims 27 and 31 are supported by cancelled claim 2. New claims 28 and 33 are supported by cancelled claim 12. New claims 29 and 34 are supported by cancelled claim 13. New claims 30 and 35 are supported by cancelled claim 14. New claim 32 is supported by claim by cancelled claim 4. No new matter has been introduced into any of the newly presented claims.

The claims have been amended to more clearly describe Applicants' invention. As discussed in the specification, the invention relates to methods for detecting the presence, absence, activity or concentration of target analytes present in a sample. To accomplish this, the invention employs a plurality of solid supports, each species of which comprises a bound binding ligand capable of specifically binding to a corresponding target analyte that is to be assayed. The claimed detection methods thus permit multiple analytes – potentially having widely varying concentrations and/or dynamic ranges of binding – to be assayed concurrently and concomitantly. The invention permits such assays to be conducted without any need to separate one analyte from another or one solid support species from other solid support species.

Support for the recitation of claims 25 and 26 that multiple sets of solid supports are employed, each species of which comprises a bound binding ligand capable of

specifically binding to a corresponding target analyte can be found, *inter alia*, at **Paragraphs Nos. 0052 and 0055**. Support for the recitation that the assays are conducted by incubation of such solid supports and target analytes in a single reaction vessel (i.e., without any need to separate one analyte from another or one solid support species from other solid support species) can be found at **Paragraph No. 0069**. No new matter has been introduced by any of the requested amendments.

II. The Rejections Pursuant to 35 U.S.C. § 102(e)

Claims 25 and 26 have been rejected pursuant to 35 U.S.C. § 102(e), as being anticipated by U.S. Patent No. 6,897,021 (Nagasawa *et al.*). Specifically, the Examiner has advised that Nagasawa *et al.* fully describes the elements of claims 25 and 26. Applicants respectfully traverse the rejection and request reconsideration.

Applicants respectfully submit that Nagasawa *et al.* is directed towards fabricating a reactive probe chip in which porous solid supports are used to bind target analytes so that they become immobilized in discrete microcompartments arranged in an ordered array on a substrate. Such arrayed microcompartmentalization is required by Nagasawa *et al.* in order to identify or otherwise characterize the immobilized target analytes. Significantly, Nagasawa *et al.* teaches that each microcompartment comprises a separate reaction vessel (please see, column 5, lines 61-63 of the document, wherein Nagasawa *et al.* state, “*a specific catalytic reaction or enzyme reaction can take place only in the compartmented regions.*” [emphasis added])). As such, binding between multiple sets of binding ligands and their corresponding target analytes never occurs in a single reaction vessel in Nagasawa *et al.*

Applicants accordingly submit that the presently claimed invention thus fundamentally differs from that of Nagasawa *et al.* As discussed above, Applicants’ invention allows multiple analytes to be analyzed *in the same reaction vessel*.

In light of the above remarks and amendments, Applicants respectfully submit that the rejection of the claims pursuant to 35 U.S.C. § 102(e) in light of Nagasawa *et al.* may be properly withdrawn.

III. The Rejections Pursuant to 35 U.S.C. § 103(a) in Light of Nagasawa *et al.* and McHugh (1994)

Claim 14 (now replaced by claims 30 and 35) has been rejected pursuant to 35 U.S.C. § 103(a) as obvious in light of Nagasawa *et al.* (U.S. Patent No. 6,897,021) in combination with McHugh (1994) (“Flow Microsphere Immunoassay for the Quantitative and Simultaneous Detection of Multiple Soluble Analytes, “Methods in Cell Biology 42, Part B (Academic Press). Nagasawa *et al.* has been discussed above. McHugh (1994) teaches basic principles and applications of flow cytometry. Applicants respectfully traverse the rejection and request reconsideration.

Applicants respectfully submit that the teachings of Nagasawa *et al.* and McHugh (1994) are not combinable. As McHugh (1994) indicates, the technique of flow cytometry “*relies upon*” the ability of the flow cytometer to accurately detect different classes of microspheres (please see McHugh (1994) at the sentence bridging pages 575-576). It is submitted that flow cytometry is thus a solution-based analytic method that cannot be conducted to analyze target analytes that have become immobilized to an ordered array probe chip. Certainly, neither Nagasawa *et al.* nor McHugh (1994) provide any teaching that would have enabled one of ordinary skill to process the Nagasawa *et al.* probe chip using McHugh (1994)’s flow cytometry techniques. Nor would it have been obvious to jettison the probe chip that is *essential* to the teachings of Nagasawa *et al.* in order to employ flow cytometry techniques. Accordingly, it is submitted that the teachings of Nagasawa *et al.* and McHugh (1994) fail to render claim 14 obvious.

Applicants further submit that even if the cited references could be meaningfully combined, McHugh (1994) fails to remedy the deficiency of Nagasawa *et al.*

As discussed above, Nagasawa *et al.* is directed towards fabricating a reactive probe chip in which porous solid supports are used to bind target analytes so that they become immobilized in discrete microcompartments arranged in an ordered array on a substrate. Such arrayed microcompartmentalization is required by Nagasawa *et al.* in order to identify or otherwise characterize the immobilized target analytes. Significantly, Nagasawa *et al.* teaches that each microcompartment comprises a separate reaction vessel. As such, binding between multiple sets of binding ligands and their corresponding target analytes never occurs in a single reaction vessel in Nagasawa *et al.* McHugh (1994) fails to disclose any approach for recovering into solution the substrate-immobilized target analytes so that they may then be analyzed using flow cytometry.

Accordingly, Applicants respectfully submit that the rejection of claim 14 pursuant to 35 U.S.C. § 103(a) as obvious in light of Nagasawa *et al.* in combination with McHugh (1994) may be properly withdrawn.

IV. Concluding Remarks

Applicants submit that the present response is complete and complies with the requirements of 35 U.S.C. §121. The Application is believed to be in condition for Allowance and early notice of such favorable action is respectfully requested. Should the Examiner have any remaining questions regarding the subject invention or its patentability, Applicants encourage the Examiner to contact the undersigned to answer such questions or provide any desired additional information.

Respectfully Submitted,

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